

**The effect of acupuncture on people
with hepatitis C virus:
A randomised controlled pilot study.**

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CERTIFICATE OF AUTHORSHIP/ORIGINALITY

I certify that the work in this thesis has not previously been submitted for a degree nor has it been submitted as part of requirements for a degree except as fully acknowledged within the text.

I also certify that the thesis has been written by me. Any help that I have received in my research work and the preparation of the thesis itself has been acknowledged. In addition, I certify that all information sources and literature used are indicated in the thesis.

Signature of Candidate

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Abbreviations - Acronyms

ANOVA	Analysis of Variance
ALT	Alanine Aminotransferase
AGDHA	Australian Government Department of Health and Ageing
AST	Aspartate Aminotransferase Tests
CAM	Complementary and Alternative Medicine
CHC	Chronic Hepatitis C
CHM	Chinese Herbal Medicine
CONSORT	Consolidated Standards of Reporting Trials
EIA	Enzyme immunoassays
ELISA	Enzyme linked immunosorbent assay
HBV	Hepatitis B Virus
HCC	Hepatocellular carcinoma
HCCNSW	Hepatitis C Council of NSW
HCV	Hepatitis C virus
HCVPWG	Hepatitis C Virus Projections Working Group
HIV	Human immunodeficiency virus
HREC	Human Research Ethics Committee
ID	Identification Number
IDU/s	Injecting drug user/s
IFN	Interferon alpha
IU	International Unit (measurement)
LFT	Liver Function Test
m/L	Millilitre
NCHECR	National Centre in HIV Epidemiology and Clinical Research
NSP	Needle and syringe program
PCR	Polymerase Chain Reaction
PBS	Pharmaceutical Benefits Scheme
QoL	Quality of Life questionnaire
RCT	Randomised Controlled Trial

RNA	Ribonucleic acid
SF36	Short Form 36 Health Survey Questionnaire
SF-36v2	Short form 36 version 2 Questionnaire
TCM	Traditional Chinese Medicine
U/L	Units per Litre
UTS	University of Technology, Sydney

Abstract

Background

The use of Complementary and Alternative Medicine (CAM) in Australia has been steadily increasing. This has resulted in many people infected with Hepatitis C Virus (HCV) consulting CAM practitioners in the hope of alleviating some of the debilitating symptoms associated with this viral infection. Chronic symptoms often lead to a reduction in everyday functional health producing a lower quality of life compared with healthy population norms or patients with other forms of liver disease. Current recommended pharmaceutical treatment has a sustained virological response in approximately 50-60% of patients. Also large numbers of people are either not suitable candidates or intolerant to treatment or do not choose this option.

In the mid 1990s, HCV residents in a Sydney alcohol and drug rehabilitation centre who were also receiving auricular (ear) acupuncture as part of their rehabilitation program, verbally reported decrease in their alanine aminotransferase (ALT) blood levels after approximately 16 acupuncture treatments administered over a three month period (Berle 1997).

Objective

To investigate whether 24 acupuncture treatments over a twelve week period has an effect on the health outcomes of people with HCV.

Design

A randomised single blind controlled pilot study with two parallel arms.

Participants

Sixteen applicants who met the eligibility criteria and agreed to participate in the study were randomised into either treatment or control group.

Outcome measures

The primary outcome measure was ALT blood levels at the completion of treatment (week 12), weeks 16 and 20. The secondary outcomes were HCV PCR quantitative (viral load test) and hepatitis quality of life (QoL) questionnaire. In addition a HCV Traditional Chinese Medicine (TCM) pattern questionnaire, acupuncture treatment credibility questionnaire and acupuncture needling sensation questionnaire were administered.

Setting

Participants were offered treatment at two clinic locations; a private clinic at Guildford and at the University of Technology, Sydney (UTS) city campus. Blinded serum pathology/testing was conducted through independent Douglass Hanly Moir Pathology clinics.

Treatment

Sixteen HCV participants were randomly allocated to two groups; one group receiving verum acupuncture treatment and the other receiving invasive sham acupuncture treatment. The treatment methodology involved the development of a TCM pattern differentiation diagnostic/outcome measure which identified 17 TCM/HCV patterns.

One participant (treatment group) left the study after eight treatments due to work commitments.

Results

No significant change was found between the two groups for ALTs, viral load or any domains of the QoL measure.

The TCM pattern questionnaire identified the primary, secondary and tertiary TCM pattern expressions for HCV within the study group. On completion of the treatment phase there was a significant reduction in the secondary and tertiary TCM pattern expression for the treatment group ($p=0.045$ and 0.037 respectively). No significant change was found for the control group.

The acupuncture credibility questionnaire identified that neither the treatment nor control group identified the type of treatment they had received; however the treatment group did perceive their treatment as more credible than the control group at week 12. There was no significant difference found between or within the two groups for the acupuncture needling sensation questionnaire.

Conclusions

Despite the small number of participants and no significant changes for ALTs, viral load or any domains of the QoL there was a significant difference in the secondary and tertiary TCM patterns.